REMARKS

Applicants respectfully request entry of the above amendments to the claims, and reconsideration of the application in light of the amendments to the claims and the arguments presented below.

The pending claims are set forth above. Claims 38, 41, 43-46 and 48 are currently pending. Claims 39and 40 have been withdrawn and claims 38, 41, 43 are amended herein. Amendment to claim 43 adds peptide fragments corresponding to amino acids 15-37, 32-57, 101-151, 115-135, 138-158, 152-172, 220-242 or 236-258 of SEQ ID NO. 243. Support for these peptide fragments is disclosed in the specification, for example on p. 30, paragraph 1.

The amendments to the pending claims are made without prejudice or disclaimer, do not constitute amendments to overcome any prior art rejections under U.S.C. §§ 102 or 103, and are fully supported by the specification as filed. No new matter has been added as a result of the above amendments. The rejections set forth in the Office Action have been overcome by amendment or are traversed by argument below.

Claims rejection under 35 USC § 101

Applicants have amended independent claim 38 to recite "purified and isolated" as suggested by the Examiner and request the Examiner to withdraw the rejection in light of the amendment. Examiner's helpful suggestion is gratefully appreciated.

Claims rejections under 35 USC § 112, first paragraph (written description)

Claims 38, 41, 43-46 and 48 stand rejected under 35 USC § 112, first paragraph, for not providing written description in such a way as to reasonably convey to one of skill in the art that the inventor(s), at the time the application was filed, had possession of the invention. The Action allegedly claims that the specification fails to disclose polypeptide comprising SEQ ID NO: 243 or an antigenic fragment thereof. Applicants respectfully traverse.

Applicants disagree with the assertion made in the Action that the specification fails to teach structure or relevant identifying characteristics of a representative number of fragments of SEQ ID NO: 243. However, to expedite prosecution of the pending claims to allowance, Applicants have amended the claims to recite that the claimed fragments are "defined by" the particular amino acid sequences and subsequences expressly disclosed in their specification. Applicants submit that their specification teaches sufficient structure and relevant identifying characteristics of a representative number of peptide fragments throughout the specification.

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For example, the specification discloses numerous fragments of SEQ ID NO: 243 (*inter alia*, on p. 12; Table 1 (on p. 73) and Table 2 (on p. 80)). The specification further provides a definition of term "fragments" (p. 23, paragraphs 2 and 3; p. 24, paragraphs 5, 6 & 7), and provides methods to make (*e.g.*, p. 31, paragraph 6) and select appropriate (antigenic) fragments (*e.g.*, p. 24, paragraphs 5, 6, 7), as well as methods to identify relevant amino acids (*e.g.*, p. 33). In addition, the specification discloses possible substitutions that can be made within SEQ ID NO: 243 to maintain its antigenicity (*e.g.*, p. 20, paragraph 6 and p. 23, last paragraph), predicted immunogenic amino acids (p. 30, paragraph 1 and 2; Table 1 on page p. 73) and serum reactive epitopes (Table 2, p. 80). Accordingly, Applicants respectfully contend that their specification discloses structural features common to members of the species and features that constitute a sufficiently substantial portion of the genus.

In light of Applicants explicit disclosure in their specification, and the amendments submitted herewith, Applicants believe that the rejection under 35 USC § 112, first paragraph has been overcome. They therefore respectfully request the Patent Office to reconsider and withdraw these grounds of rejection.

Claims rejections under 35 USC § 112, first paragraph (enablement)

Claims 38, 40 (withdrawn herein), 41, 43-46 and 48 stand rejected under 35 USC §112, first paragraph, for failing to provide an enabling disclosure. The Action states that the specification fails to disclose all *S. pneumoniae* antigenic fragments that would be included due to the use of open claim language for fragments of SEQ ID NO: 243. More specifically, the Action asserts that using such open claim language would encompass any unknown fragment without any structure or other identifying characteristic. Moreover, the Action asserts that the specification does not disclose how to make such fragments retaining the antigenicity of the full length protein. While not acquiescing to these grounds of rejection or the rationale supporting it, in order to further prosecution of the pending claims to allowance, Applicants have amended their claims to recite that the claimed antigenic fragments are defined by the expressly-recited amino acid sequences and subsequences. In light of these amendments, Applicants respectfully contend that the claims reciting fragments of SEQ ID NO: 243 are fully enabled by their specification.

Further, the Action states on page 8 that although the specification is enabling for isolated *S. pneumoniae* antigens comprising SEQ ID NO: 243 and its recited antigenic fragments, the specification fails to enable the disclosed *S. pneumoniae* antigens as being

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immunologically reactive and capable of generating a humoral or cellular immune response t at could be used to treat or prevent *S. pneumoniae* infection. The Action further asserts that the specification fails to disclose "critical residues" that are important for treating or preventing *S. pneumoniae* infection or identifies any changes in SEQ ID NO: 243 that can produce fragments useful for treating or preventing *S. pneumoniae* Infection. The Action asserts that in view of unpredictability of art, this lack of teaching of the specification would require undue experimentation on part of one of skill in art to practice the claimed invention throughout its full scope.

Applicants respectfully submit that the specification provides clear guidance to one of skill in the art for making antigenic fragments of the polypeptide of SEQ ID NO: 243 and demonstrates immune response thereto. For example, the specification in Example 3 (and corresponding results shown in Table 1 on p. 73) shows regions of the polypeptide that are identified as immunogenic. In Example 4 (and corresponding results shown in Table 2 on p. 80) the specification discloses specific serum reactive epitopes. In addition, Example 7 (on p. 58) shows that the highest degree of protection was achieved by antigens representing SEQ ID NO: 243 (SP2216) along with other antigens. More specifically, Fig. 10 shows protection by the full length polypeptide of SEQ ID NO: 243 and fragments thereof. Thus, Applicants respectfully contend that the evidence contained in the specification as filed establishes that antigenic fragments of the invention are capable of generating an immune response using an art-recognized animal model for immunogenicity. The specification further teaches one of ordinary skill in the art how to use the claimed antigenic fragments of the polypeptide of SEQ ID NO: 243 to generate an immune response in an animal, as well as substitutions that can be made with SEQ ID NO: 243 to maintain its antigenicity (e.g., p. 20, paragraph 6 and p. 23, last paragraph). Furthermore, the specification at Example 4, Table 2 (p. 80) shows that antigenic fragments of SEQ ID NO: 243 could be detected by using human antisera, indicating that humans are capable of generating and in fact do generate an immune response to the polypeptide and antigenic fragments of SEQ ID NO: 243. The specification also discloses the use of the polypeptide of SEQ ID NO: 243 or its antigenic fragments in a pharmaceutical composition as vaccine.

Based on this disclosure, Applicants respectfully submit that the specification provides enablement for their invention as instantly claimed their entire scope, and that one of skill in art would not exercise undue experimentation to make or use claimed invention. Accordingly, Applicants respectfully request that the Examiner withdraw this ground of rejection.

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Claims rejections under 35 USC § 112, second paragraph (indefiniteness)

Claims 40 (withdrawn herein), 41, 43-46 and 48 stand rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as invention.

More specifically, Claim 40 (withdrawn herein) and claim 41 stand rejected on 35 U.S.C. §112, second paragraph grounds for reciting "(SEQ ID NO: 243)" and for using laboratory identification "Sp2216" to identifying the antigenic polypeptide. Applicants have removed the parenthesis as suggested by the Examiner, and have amended the claim in order to clarify the claimed invention. Applicants thank the Examiner for helpful suggestion. Applicants respectfully contend that the claim as amended overcomes the asserted grounds of rejection, and requests the Examiner to withdraw this ground of rejection.

Claims rejections under 35 USC § 102

Claims 38 and 39 (withdrawn herein) stand rejected under 35 USC §102(b) as being anticipated by McCool *et al*. (J. Exp. Med., 2002). The Office Action states that the McCool reference discloses a 22KDa antigen and identified it as N-terminal region of pneumococcal surface antigen A. Without acquiescing to the correctness of these assertions, Applicants have amended the claims by limiting the instant claimed invention to SEQ ID NO: 243. The McCool reference only discloses PspA protein which has an amino acid sequence different from SEQ ID NO: 243 that is recited as an explicit limitation of the pending clams. The McCool reference therefore does not teach each and every limitation of claims as amended. Hence, Applicants request reconsideration, and withdrawal of rejection under 35 USC §102(b).

Claims 38, 40 (withdrawn), 41, 42 (withdrawn), 43-45 and 48 stand rejected under 35 USC §102(b) as being anticipated by Masignani et al. (WO 02/077021). The Office asserts that the Masignani reference discloses an isolated *S. pneumoniae* antigen with SEQ ID NO: 4652 that is 100% identical to the claimed SEQ ID NO: 243, along with pharmaceutical compositions comprising therapeutic amount of peptide SEQ ID NO: 4652. Applicants respectfully disagree and submit that the Masignani reference merely discloses the amino acid sequence of an open reading frame of *S. pneumoniae* genomic DNA without disclosing whether in fact this polypeptide is actually produced by the bacteria. Moreover, the reference fails to disclose that the putative polypeptide is antigenic. Further, the Masignani reference fails to provide any teaching with regard to peptide fragments, particularly fragments that could produce protective

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immunogenic response. In particular, the Masignani reference does not identify with any antigenic fragments, and specifically does not identify the fragments identified by Applicants that are reactive with hyperimmune sera.

Thus, the Masignani reference does not disclose each and every limitation of Applicants' claims as required under 35 U.S.C. §102(b). Applicants respectfully submit that the Masignani reference does not anticipate their amended claims, and respectfully request that the Office withdraw this ground of rejection.

CONCLUSION

Applicants respectfully contend that the instant application is in condition for allowance in view of the claim amendments and arguments presented above, and respectfully requests it be allowed. If the Examiner believes that a telephone or personal interview would expedite prosecution of the instant application, the Examiner is respectfully invited to call the undersigned attorney at (312) 913-0001.

Respectfully submitted,
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